ASSESSMENT OF HUMAN EXPOSURE TO CIGARETTE SMOKE CONSTITUENTS: PILOT STUDY RESULTS FOR CARBON MONOXIDE. R D Kinser[1], B L Nelson[1], H-J Roethig[1], R-A Walk[1], J Oey[1], A R Tricker[2], D E Leyden[3]. [1]Philip Morris U.S.A., Richmond, VA; [2]Philip Morris Products SA, Neuchatel, Switzerland; [3]Hartfield, VA, USA

This pilot study was conducted to aid in the development of the experimental design for a large study of exposure of adult smokers in the U.S. to selected cigarette smoke constituents.

The study included 69 adult smokers (21 years of age or older) of any brand of 3.0 – 6.9 mg tar yield (FTC method) of manufactured cigarettes and 68 non-smokers. For assessment of exposure levels of carbon monoxide (CO), CO in exhalate and carboxyhemoglobin (COHb) were measured on weeks 1, 2, 3 and 6 of the six-week pilot study. The average level of CO in the exhalate of smokers was 25.3 ± 14.4 ppm, while that for non-smokers was 5.6 ± 1.8 ppm. These differences between smokers and non-smokers are statistically significant ($p \leq 0.0001$). The mean COHb levels over the same timeframe were $4.3 \pm 2.8\%$ for smokers and $0.6 \pm 0.4\%$ for non-smokers. These differences between smokers and non-smokers are also statistically significant ($p \leq 0.0001$). At each of the four measurements COHb levels were statistically significantly higher for smokers than non-smokers ($p \leq 0.0000$) for both the male and female groups. For many of the non-smoker measurements of COHb values below the limit of quantitation (LOQ) of 0.3% were obtained. Statistical calculations were conducted to explore four ways of handling these results: omission of the data from the data set; setting values < LOQ to 0; setting values <LOQ to the LOQ; and setting values <LOQ to O.5 LOQ. None of these approaches altered the statistical comparisons reported above.

Based on additional statistical and analytical measure of intra- and inter-individual variability as well as response analyses versus smoking dose (based on questionnaires) we conclude that both CO in exhalate and the COHb measurements provide a reliable measure of CO exposure of adult U.S. smokers.

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